

75747-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/7/2010

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:

75747-2

Date of Issuance:

1-7-2010

Term of Issuance:

Unconditional

Name of Pesticide Product:

BOTRY-Zen®

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Botry-Zen Limited
21 Willis Street, P.O. Box 5664
Dunedin, New Zealand

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c)(5). You are required to:

1. Submit and/or cite all data required for registration/ re-registration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Revise the EPA Reg. No. entry to read, "EPA Reg. No. 75747-2"
3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Date:

07 January 2010

Keith A. Matthews, Acting Director,
Biopesticides and Pollution Prevention Division

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P	7511P	7511P				
SURNAME	Greenway	Reynolds	Puffy	Matthews				
DATE	1/7/2010	1/7/10	1/7/10	07 JAN 10				


EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

BOTRY-Zen®

Biofungicide

 (For Organic Production) (For Use in Organic Production)

ACTIVE INGREDIENT:

Ulocladium oudemansii (U3 Strain)* 45.00%

OTHER INGREDIENTS: 55.00%

TOTAL: 100.00%

*Contains not less than 2.5×10^8 cfu/gram.

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

See (back) (side) panel for additional precautionary statements and directions for use.

EPA Reg. No.: (pending as File Symbol 75747-E)

Net Weight: 9 lbs (4 kg)

EPA Establishment No.: XXXXX-XX-XX

(Use By: (date 11 months from date of manufacture)).

(Batch No. / Lot No.: XXX)

Manufactured by:

Botry-Zen Limited
21 Willis Street, PO Box 5664
Dunedin, New Zealand
www.botryzen.co.nz

Distributed by:

(U.S. name and address –to be determined)

ACCEPTED

JAN 07 2010

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 75747-2

BOTRY-Zen®; EPA Reg. No. (pending as File Symbol 75747-E)

MASTER LABEL - Label version (6) dated October 19, 2009

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - CAUTION. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes or clothing. Avoid breathing spray mist. Wear safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE): Applicators and other handlers must wear long-sleeved shirt and long pants, waterproof gloves, and shoes plus socks. Mixer/loaders and applicators, not in enclosed cabs, must wear a dust/mist-filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning / maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations: Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards: Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean highwater mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment (PPE), and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: coveralls, waterproof gloves, shoes plus socks.

Do not apply this product through any type of irrigation system.

General Information: BOTRY-Zen® is a biological control agent developed specifically for the control of *Botrytis cinerea* and *Sclerotinia sclerotiorum*.

BOTRY-Zen® is a live spore preparation of a non-pathogenic saprophytic fungus. BOTRY-Zen® acts as a biological control agent by competing for the same ecological niche as the plant pathogens *Botrytis cinerea* and *Sclerotinia sclerotiorum*.

When BOTRY-Zen® spores are deposited on the dead and senescent plant debris, and the right environmental conditions exist, they germinate and colonize. The developed mycelium will proceed to colonize the dead tissue and, if conditions are suitable, additional sporulation can occur and these new spores are then available to colonize remaining debris.

BOTRY-Zen® aggressively occupies the same physical space and out competes *Botrytis* spp. and *Sclerotinia* spp. for the nutrients in the dead and senescing plant tissue; it is a true antagonist. BOTRY-Zen® is non-invasive and causes no damage to live plant tissue. With this mechanism of action, it is highly unlikely that resistance to BOTRY-Zen® will develop.

Integrated Pest Management: Integrate BOTRY-Zen® into an overall pest management strategy whenever fungicide use is necessary. Follow practices known to reduce disease development. Consult local agricultural authorities for specific IPM strategies developed for your crop(s) and location.

Pre-Harvest Interval: BOTRY-Zen® can be applied up to and including the day of harvest, except as noted. See Application Rates table for crop-specific application frequency information.

Mixing and Application Instructions:

MIXING: Dilute BOTRY-Zen with water and apply in conventional spray equipment. Partially fill the spray tank with clean water and begin agitation. Add the specified amount of BOTRY-Zen® to the tank. Finish filling the tank to the desired volume to obtain the proper spray concentration. Add a surfactant or a non-ionic adjuvant to improve product wetting / spreading. Maintain agitation continuously while spraying. Use spray mixture immediately. Do not allow spray mixture to stand overnight or for prolonged periods.

APPLICATION: Apply BOTRY-Zen® using conventional spray equipment to the point of saturation. Good coverage and wetting is required. The amount of spray solution to apply will vary depending on the type of crop. Most row crops will require up to 100 gallons of spray per acre. Apply in sufficient water to achieve thorough coverage.

COMPATIBILITY: Consult your BOTRY-Zen representative for more information on BOTRY-Zen® compatibility with pesticides, surfactants and fertilizers. BOTRY-Zen® may be tank mixed with some fungicides. Do not tank mix BOTRY-Zen® with more than one product. Consult specific product labels for additional information or restrictions concerning tank mixing. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures. It is always advisable to conduct a spray compatibility test when you plan to mix this product with another product. To determine the physical compatibility of this product with other

products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry formulations first, then flowables, and then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding products to the spray tank.

BOTRY-Zen® has been evaluated for phytotoxicity on a variety of crops under various normal growing conditions. However, testing all crop varieties, in all mixtures and combinations is not feasible. Prior to treating entire crop, test a small portion of the crop for sensitivity.

Application Rates:

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Crops	Disease	Lb/Acre	Notes
Asparagus	Botrytis Blight	4	Begin application soon after emergence and when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Berries, such as: Blackberry Blueberry Bushberry Caneberry Cranberry Currants Elderberry Gooseberry Huckleberry Loganberry Raspberry	Botrytis Blight	4	Apply during early bloom and repeat on a 7 to 10 day interval or as needed.
Bulb Vegetables, such as: Garlic Leeks Onions Shallots	Botrytis Leaf Blight Botrytis Neck Rot <i>Botrytis squamosa</i> <i>Botrytis</i> spp.	4	Begin application when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Cucurbit Vegetables, such as: Cucumbers Melons Squash Zucchini	Gray Mold (<i>Botrytis cinerea</i>)	4	Begin application soon after emergence or transplant and when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Fruiting Vegetables, such as: Eggplant Okra Pepper Tomato Tomatillo	Gray Mold (<i>Botrytis cinerea</i>)	4	Begin application soon after emergence or transplant and when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Grapes	Gray Mold (<i>Botrytis cinerea</i>)	4	Apply at early and late bloom, then again when the berries are pea-sized, and finally at pre-bunch closure. Spray onto vines ensuring the bunch zone is well covered.

Kiwifruit	Gray Mold (<i>Botrytis cinerea</i>) <i>Sclerotinia sclerotiorum</i>	4	Make applications at 30% and 80% flowering. Do not apply after the bloom period.
Leafy Vegetables, such as: Broccoli Cabbage Celery Collards Lettuce Spinach	Sclerotinia Head and Leaf Drop <i>Sclerotinia</i> spp.	4	Within 7 days of thinning or transplanting apply as a directed spray with multiple nozzles per each seed line in sufficient water to ensure thorough coverage of lower plant leaves and surrounding soil surface. Repeat applications on 7 to 14 day intervals if conditions for disease development persist. Light irrigation after application to incorporate the product can improve disease control.
Legumes, succulent and dried, such as: Field beans Lentils Peas Peanuts Soybeans	<i>Sclerotinia sclerotiorum</i> Sclerotinia Stem Rot	4	Begin application soon after emergence or transplant and when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Ornamental Plants Bedding Plants	Gray Mold (<i>Botrytis cinerea</i>)	4	Ornamentals grown in nurseries and greenhouses. Begin application when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Passionfruit	Gray Mold (<i>Botrytis cinerea</i>) <i>Sclerotinia sclerotiorum</i>	4	Begin application when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Root, Tuber and Corm Vegetables, including: Beets Carrots Cassava Ginger Potato Radish Sugar beets Sweet potato Yams	Gray Mold (<i>Botrytis cinerea</i>) <i>Sclerotinia sclerotiorum</i>	4	Begin application soon after emergence or transplant and when conditions are conducive to disease development. Repeat on 7 to 10 day intervals or as needed.
Strawberries	Gray Mold (<i>Botrytis cinerea</i>)	4	Begin application at or before flowering. Repeat on 7 to 10 day intervals or as needed up until harvest

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place at or below 68°F (20°C). Store in original container only. Keep container tightly closed when not in use.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances. If outside container is contaminated, dispose of in the same manner as the bag.

WARRANTY STATEMENT

Botry-Zen Limited warrants to those persons lawfully purchasing this product that at the time of the first sale of this product by Seller that this product conformed to its description and was reasonably fit for the purposes stated on the label when used in accordance with Seller's directions. Buyers and users of this product assume the risk of any use contrary to such directions. EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTEE, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO. To the extent permitted by state law, the Seller's liability for any breach of warranty shall not exceed the purchase price of the material as to which a claim is made.

To the extent permitted by state law, Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, or without the fault or negligence of the Seller, or from failure to follow the label.

OPTIONAL LABEL CLAIMS

- Biofungicide.
- Biological control of (*Botrytis cinerea*) (*Sclerotinia sclerotiorum*).
- The Biological Solution for *Botrytis cinerea* and *Sclerotinia sclerotiorum*.
- No pre-harvest interval (PHI) for most crops.
- Low Reentry Interval (REI).